

# **Electronic Nicotine Delivery Systems AKA Electronic Cigarettes**

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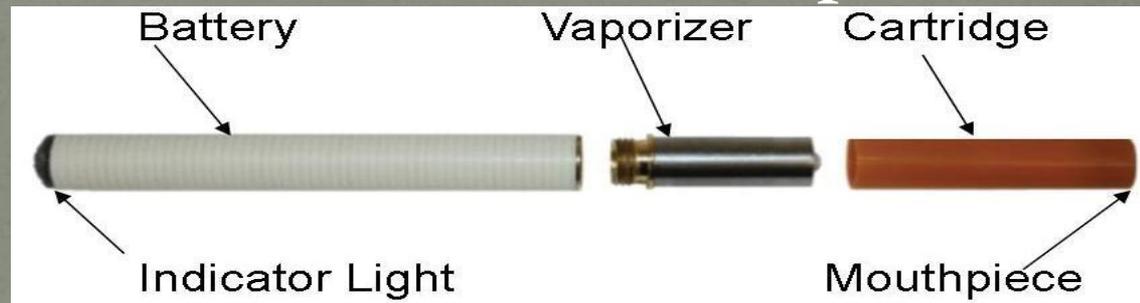
Status in the U.S.

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Comprehensive Tobacco Control Program, MoDHSS

522-2824

# What are electronic nicotine delivery systems or electronic cigarettes (e-cigarettes)?

- Products designed to deliver nicotine or other substances to user in vapor form



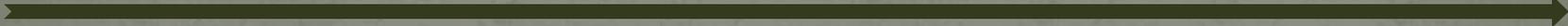
- Battery: heating element, rechargeable
- Vaporizer (atomizer): converts cartridge contents into vapor inhaled by user
- Replaceable/refillable cartridge: contains nicotine and/or other chemicals – amount varies up to 20 mg nicotine, some with 0 mg

# Electronic nicotine delivery systems (ENDS)

- Made to look like cigarettes, cigars, pipes, hookahs; may also look like pens or USB memory sticks

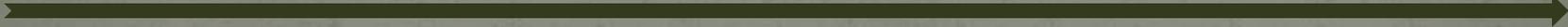


## ENDS/e-cigarettes



- Using these products is commonly referred to as “vaping” since they produce vapor, not smoke
- Many young people don’t recognize the term “electronic cigarette” – they use “vape pens”
- Are promoted by manufacturers, sellers and users as safe - producing *water* vapor not smoke

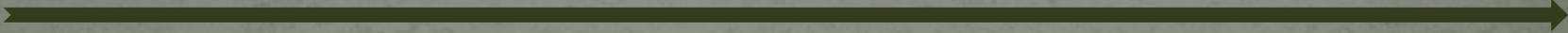
## ENDS/e-cigarettes



Probably more questions than answers!

- Are they tested?
- Are they safe?
- Are they a cessation device?
- Who is using them and why?
- What is the public health stance?

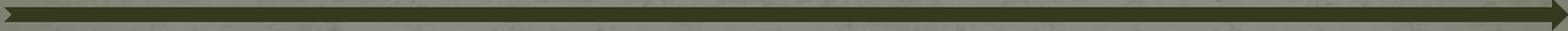
# US Food & Drug Administration (FDA) regulation of tobacco products



Under the authority of the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA), the FDA Center for Tobacco Products currently regulates

- cigarettes
- cigarette tobacco
- roll-your-own tobacco
- smokeless tobacco

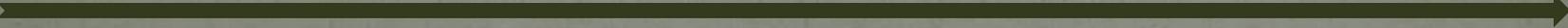
# What is the status of ENDS with FDA?



- ❑ FDA has not evaluated any ENDS/e-cigarettes for safety or effectiveness
- ❑ Early on, in limited laboratory studies, FDA found issues indicating substandard or non-existent quality control\*:
  - Cartridges labeled as containing no nicotine did contain nicotine
  - 3 different cartridges with the same label gave off very different amounts of nicotine with each puff

\*Subsequent studies by independent researchers have found the same

## From FDA's "Tobacco Products" website

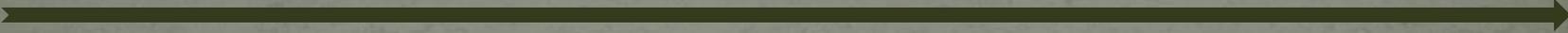


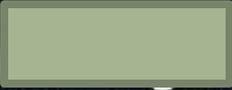
[www.fda.gov/NewsEvents/PublicHealthFocus](http://www.fda.gov/NewsEvents/PublicHealthFocus)

As the safety & efficacy of e-cigarettes have not been fully studied, users currently have no way of knowing:

- whether e-cigarettes are safe for their intended use
- how much nicotine or other potentially harmful chemicals are being inhaled in use
- if there are any benefits associated with using these products

And yet .... this is prominent on one  
e-cigarette website

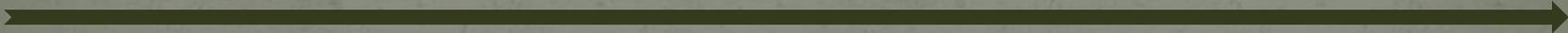


*"As a non-smoker I welcome it, because **it won't harm me or my kids**. I hope actually it  takes off and the other stuff goes away."*

-Tracy Byrnes

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## ENDS/e-cigarettes - status with FDA



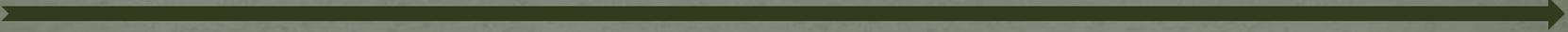
- ❑ In 2009, due to marketing claims that e-cigarettes help people quit smoking, FDA attempted to regulate them as drug-delivery devices
- ❑ This failed in December 2010 when a federal court stated FDA did not have this authority

## ENDS/e-cigarettes - status with FDA

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- However, the court said FDA *could* exercise authority over e-cigarettes as a tobacco product under the FSPTCA
- In April 2014, FDA issued proposed regulations identifying ENDS/e-cigarettes as tobacco products with:
  - restrictions on sales to minors
  - pre-market review
  - mandated ingredient listing

## Cost of ENDS/e-cigarettes



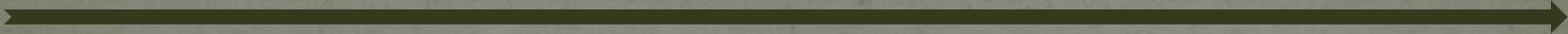
- ❑ Typical starter kit costs between \$60 to \$150 including:
  - the device & battery
  - several cartridges or bottles of “e-juice”
- ❑ A pack of 5 cartridges costs about \$10
- ❑ A pack of the cheapest cigarettes in Missouri costs \$3-4 with the high at about \$5
- ❑ Each full-strength cartridge equals about a pack of cigarettes, depending on how much a person smokes

# Nicotine



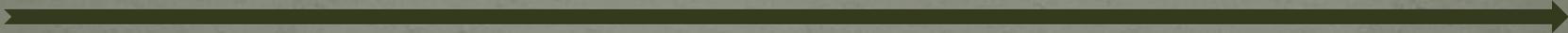
- Is **addictive**
- Is **toxic** to developing fetuses
- Is a **poison**

# Nicotine



- ❑ An average combustible cigarette yields about **1 milligram (mg)** of *absorbed* nicotine when smoked
- ❑ The yield of *absorbed* nicotine in “vaping” is unknown; it still being scientifically tested
- ❑ One e-cig website says **each** of their cartridges is **equivalent** in nicotine to about **20 cigarettes**
- ❑ Nicotine amounts in cartridges & fluids vary, starting at zero

## Liquid nicotine or “e-juice”



- ❑ Consumers can purchase refill nicotine liquid for the cartridge or vape chamber/pen in small bottles
- ❑ E-juice comes in multiple flavors
- ❑ Bottles contain up to **7 grams** of nicotine

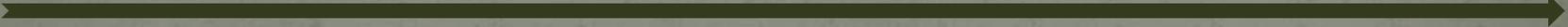
## Liquid nicotine or “e-juice”

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- ❑ The estimated fatal dose of nicotine for adults is 30 - 60 **mg**
- ❑ The estimated fatal dose of nicotine for children is only **10 mg** - approximately 4 drops of a maximum strength refill solution

This risk is more consistent with nicotine-based **pesticides**, rather than traditional tobacco products, and poses a danger via inhalation, ingestion, and skin contact

## Nicotine – a **POISON!**

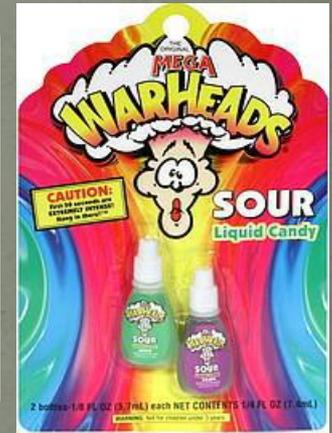


- The number of poisoning cases linked to ENDS/e-cigarettes liquids was 1,351 in 2013, a **300%** increase from 2012
- According to the National Poison Data System, these number are on pace to **double** in 2014

# Why so many poisonings?



Can you find the candy?

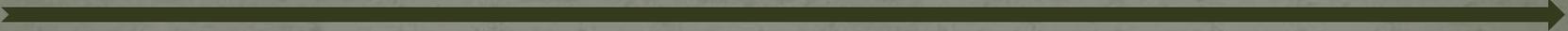


# Marketing & commercial appeal

**ENDS/e-cigarettes are promoted heavily online & are more widely searched than snus & NRTs (nicotine replacement therapy – gum, patches)**

The screenshot shows a Windows Internet Explorer browser window displaying the website 'Electronic Cigarette Reviews and Blog'. The address bar shows the URL 'http://www.e-cig.org/category/products-updates/electron...'. The page title is 'Electronic Cigarette Reviews and Blog' with the tagline 'NO SMOKING, JUST VAPING'. The navigation menu includes 'E-Cigarette Blog', 'Electronic Cigarettes for Sale', 'Discount Coupons', 'Reviews', 'Affiliate Programs', and 'Pages'. A search bar is visible on the right. A prominent banner advertises 'BUY A STARTER KIT, SAVE 15% ON CARTS' with a 'Shop Now' button. Below the banner, the current category is 'Electronic Cigarette Reviews'. The featured article is titled 'Vapor4Life E-Cig Kit Discounts and Coupon Codes' by Jimmy Tank, dated July 17, 2013. The article text describes Vapor4Life's core brands (Vapor Titan, Dial-A-Volt, Vapor Zeus) and their features. Social media sharing icons for Facebook, Twitter, Dribbble, LinkedIn, and StumbleUpon are present. Below the article, there is a section titled 'Our New Recommended E-Cigarette Supplier: Vapor4Life' by Jimmy Tank, dated April 3, 2013. The article text mentions the addition of Vapor4Life to the list of preferred vendors. The browser's taskbar at the bottom shows the Start button, several open applications (5 M..., 2 W..., 3 I..., 4 A..., 3 M...), and the Microsoft Office Word application. The system tray shows the time as 1:15 PM and the volume level at 70%.

## From FDA's Tobacco Products' website



**It is not known if e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death**

# Marketing & commercial appeal

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Why e-cigarettes probably appeal to youth :

- high-tech design
- easy availability online or via mall kiosks
- many flavors of cartridges – exotic, candy, fruit, alcohol, etc.
- glamorous and/or edgy marketing
- appeal to style, fabulous accessories
- “disguise” as other products (e.g. pens)





High  
tech



# On-line availability

Dragonfly eCigs

http://www...

File Edit View Fav

Favorites Goo... 100... Dic... Map... Wea... Fac... Tob... USP... Are... Mo-X usa...

http://dh... My Busi... Smoke -... what is ... Drag... x

Page Safety Tools

Languages: Currencies: US Dollar Shopping Cart: 0 items

Home page New products Specials My account Contact us

Nothing to say here.... It's the ProVari (and Mini)... The "Cadillac" of Vaping.

QUICK FIND

Use keywords to find the product you are looking for. [Advanced Search](#)

READ WHAT OTHERS ARE SAYING

Displaying 1 to 6 (of 1074 reviews) Result Pages: 1 2 3 4 5 ... [\[Next >>\]](#)

1000ml DragonJuice - USA Made - (18mg) Medium Date Added: Thursday 04

Internet 100%

Start 5 M.. Dra... misc Micr... Micr... July ... 3:15 PM

# Flavors

- The only flavor of cigarettes is menthol
- E-cigarettes are available in many flavors including candy, fruit, spices, menthol



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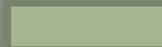


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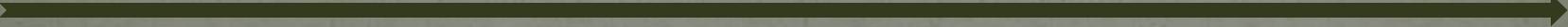
## “Edgy” marketing

E-cigarettes are advertised as:

- A better-smelling, cheaper, guilt-free alternative to smoking
- A way to circumvent smokefree laws & policies



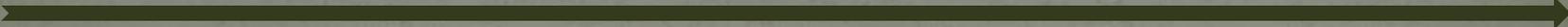
# Why be concerned?



Using ENDS/e-cigarettes in public, smokefree areas could undermine smokefree policies & youth prevention efforts by:

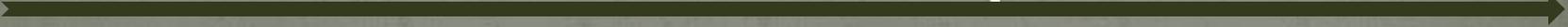
- Making enforcement more difficult
- Giving the appearance that smoking is acceptable
- People are being exposed in the belief that the vapor is safe

# Are ENDS/e-cigarettes safe?



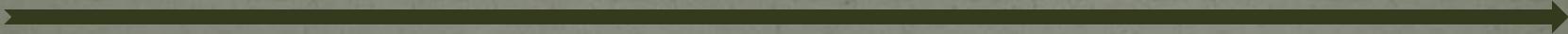
- ❑ It is claimed they emit “harmless water vapor” so they must be safe
  - Is it “just” water vapor?
  - Is “automatically” safe if water is the “base”?
- ❑ Testing is limited, the safety is **not** known for either the user (“vaper”) or those exposed to the vapor
- ❑ Research is showing.....

## What is in the vapor?



- ENDS aerosol is not “water vapor” it contains:
  - nicotine
  - propylene glycol
  - fine & ultrafine (UF) particles
  - low levels of toxins known to cause cancer (at least 10 have been identified)
  - nanoparticles of chromium, nickel, tin

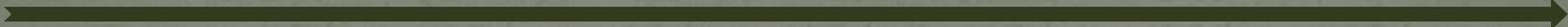
# Recent Research - Safety



*Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette (EC) Cartomizer Fluid and Aerosol, PLOS One, March 2013*

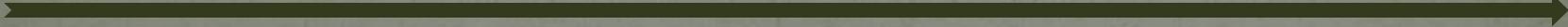
- ❑ Concentrations of 9 of 11 **metallic** elements in EC aerosol (vapor) were **higher than or equal to** the concentrations in cigarette smoke
- ❑ Presence of metal and silicate particles in the vapor demonstrates the need for improved quality control in EC design and manufacture
- ❑ Studies are needed on how EC vapor impacts the health of users and bystanders

# ENDS/e-cigarette user health issues



- Aerosol has higher concentration of UF particles than cigarette smoke
- Many of the UF particles cause respiratory problems - short term use has been shown to increase respiratory resistance and impair lung function
- Exposure to fine & UF particles may exacerbate asthma & constrict arteries, triggering a heart attack
- Although propylene glycol is FDA approved for use in some products, inhaling vaporized nicotine in propylene glycol is not
- Some studies show that heating propylene glycol changes its chemical composition, producing small amounts of propylene oxide, a known carcinogen

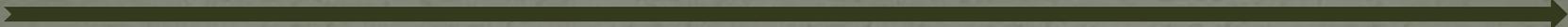
## Recent Research – Effect on non-users



*Does e-cigarette consumption cause passive vaping? Indoor Air, April 2013*

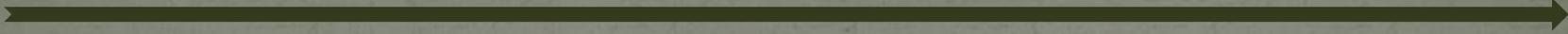
- ❑ Fine particles, ultrafine particles, and volatile organic compounds were found *in the air* in **increased quantity** after the use of an e-cigarette
- ❑ The inhaled aerosol undergoes changes in the human lung
- ❑ Passive vaping must be expected from the use of e-cigarettes

## Secondhand ENDS/e-cigarette vapor?



- They may be less polluting than cigarettes, but they still pollute the air
- Emissions expose non-users to:
  - nicotine absorption at levels comparable to secondhand smoke
  - UF particles
  - low levels of toxins known to cause cancer
- Same health effects
- Long term health effects on non-smokers are unclear, but science on negative consequences is mounting

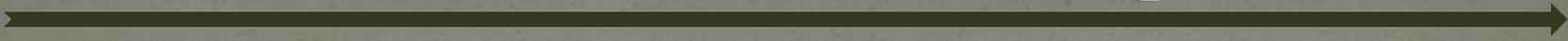
# Recent Research – Awareness/Beliefs



*Characteristics Associated With Awareness, Perceptions, and Use of Electronic Nicotine Delivery Systems Among Young US Midwestern Adults, AJPH, March 2013*

- ❑ More than 2/3 of young adults were aware of ENDS/e-cigarettes
- ❑ A small proportion had tried/used them in past 30 days
- ❑ Despite the lack of scientific evidence, a considerable proportion of users & non-users thought they:
  - can help people quit smoking
  - are less harmful and less addictive than cigarettes

# Recent Research – Users Opinions



*Vaping profiles and preferences: an online survey of electronic cigarette users, Addiction Research, Feb. 2013*

- ❑ E-cigarettes :
  - were satisfying to use
  - reduced cravings for tobacco cigarettes
  - were associated with very few immediate side effects
  - tended to be used for a longer duration than NRT
- ❑ Future research should concentrate on:
  - possible health risks associated with long-term use
  - efficacy for smoking cessation, including possible differences in brands or products
  - abuse potential

## Who is using ENDS/e-cigarettes in Missouri?

Adults – January – April 2014 - 9% of tobacco user callers to Missouri

### Tobacco Quitline

- 43% use to cut down
- 57% use to quit
- 11% use when can't use other products
- 38% use every day
- 20% use more than one cartridge a day while 30% use one or less

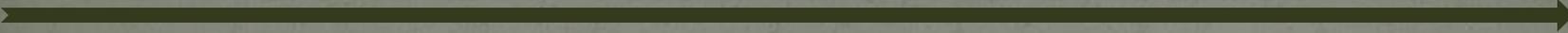
# Who is using ENDS/e-cigarettes in Missouri?



Youth - 2013 (Youth Risk Behavior Survey  
& Youth Tobacco Survey)

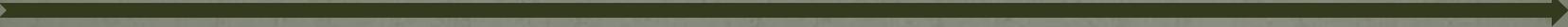
- Middle school: 3.5% of all but
  - 30% of current smokers and 2% of non-smokers
- High school: 12.4% of all but
  - 49% of current smokers and 6% of non-smokers

# Cessation product?



- ENDS are **not** FDA-approved cessation products
- 4 prescription & 3 non-prescription smoking cessation products *are* FDA-approved:
  - RX: Varenicline, Bupropion, Nicotine Inhaler, Nicotine Nasal Spray
  - OTC: nicotine replacement patches, gum, lozenges
- These products have been scientifically shown to be effective for smoking cessation *and* are safe when used as directed

# Recent Research – Cessation Potential

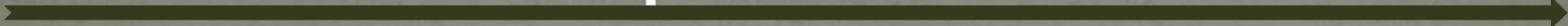


*Use of Electronic Cigarettes Among State Tobacco Cessation Quitline Callers,  
Nicotine & Tobacco Research, May 2013*

*E-cigarette user groups were **significantly less likely to have quit** smoking 7 months after first calling the Quitline, compared with participants who had never tried e-cigarettes*

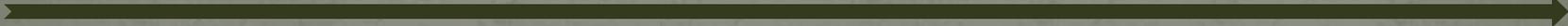
Note: Authors affiliated with Alere Wellbeing, Inc. a Quitline Provider

## Other issues– initiation & cessation potential



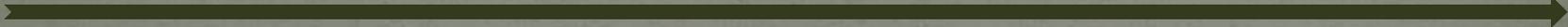
- Surveys are showing patterns of dual use (both ENDS and cigarettes) by both adults & youth
- Nicotine is addictive & hard to break:
  - current smokers may not realize they have not kicked the addiction
  - former smokers, believing ENDS are safe, may return to nicotine addiction
- The high-tech, attractive products & marketing are “glamorizing” & potentially “re-normalizing” smoking

## Public health approach - cessation



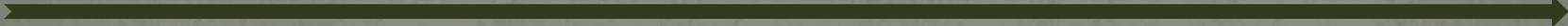
- ❑ We *can* say there is no scientific evidence that e-cigarettes help smokers quit
- ❑ We *do* know that they are a nicotine delivery device – and nicotine is addictive
- ❑ We should recommend **only** known, tested, safe, products for those trying to quit

## Public health approach – cessation & secondhand smoke exposure



- ❑ Studies are being done, but with many brands and too few studies, conclusions are not definite
- ❑ There are too many unknowns
  - We can *not* say they are safe – but it does appear as if the vapor is not “harmless water vapor”
  - We can *not* say that they are unsafe – they may indeed be safer than combustible cigarettes

## Public health approach – secondhand smoke exposure



- Because of the unknowns surrounding the vapor

and

- Because e-cigarettes resemble smoking

**Public health is taking a cautious approach**

- Most prohibit them in smokefree / tobacco-free policies for the organization
- And encourage them in policies for communities and businesses